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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/963,288 11/03/97 NORSTEDT

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EXAMINER

HM12/0815

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ART UNIT

PAPER NUMBER

1632

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 08/963,288	Applicant(s) NORSTEDT ET AL.	
	Examiner Anne-Marie Baker	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,7-11,15-17,19-21,23-32,34-36,39-42,44-50 and 52-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-11,15-17,19-21,23-32,34-36,39-42,44-50,52 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>26</u> | 6) <input type="checkbox"/> Other:  |

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### DETAILED ACTION

The amendment filed May 22, 2001 (Paper No. 25) has been entered. Claims 1, 5, 8, 10, 19, 23, 27, 30, 31, 34, 44, and 46-50 have been amended. Claims 51 and 54 have been cancelled.

Claims 1, 2, 5, 7-11, 15-17, 19-21, 23-32, 34-36, 39-42, 44-50, 52, and 53 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous Office Action are hereby withdrawn.

### *New Matter*

The amendment filed May 22, 2001 (Paper No. 25) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: an expression vector comprising six enhancer elements, and further wherein at least one of the enhancer elements consists essentially of the nucleotide sequence TTCTGAGAA and the remaining enhancer elements comprise the nucleotide sequence TTCTGAGAA (Claim 8), and the vector of claim 9, wherein at least one of the remaining enhancer elements is the nucleotide sequence of SEQ ID NO: 1 (Claim 10). The specification does not disclose or contemplate vectors of these types.

Applicant is required to cancel the new matter in the reply to this Office action.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 7-11, 15-17, 19-21, 23-32, 34-36, 39-42, 44-50, 52, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 39, 40, 51, and 52 are indefinite because the preamble recites that the DNA construct comprises “a structural gene for a desired protein or polypeptide”, but the DNA construct used to transfect the host cell does not comprise a structural gene. Thus, the preamble is in conflict with the rest of the claim and the metes and bounds of the claim are not clearly set forth. It is suggested that the claim language recite in part (a) “providing a DNA construct comprising six copies of an enhancer element upstream of a promoter and a structural gene downstream from said promoter”.

Claims 1, 2, 39, 40, 51, and 52 are indefinite in their recitation of “transfecting the eukaryotic host cell to incorporate the DNA construct” because it is unclear where the DNA construct is incorporated. Given that the preamble indicates that the construct should be incorporated into the genome, it is suggested that the claim language recite “transfecting the eukaryotic host cell to incorporate the DNA construct into the genome of the host cell”.

Claims 5, 7-11, 15-17, 23-26, 34-36, 50, and 53 are indefinite in their recitation of “wherein the enhancer element is responsive to both lactogenic hormones and somatogenic hormones” because the claims are directed to the element alone, and the element consisting essentially of the nucleotide sequence TTCTGAGAA in isolation would not be hormone responsive. The element must be incorporated into a DNA

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construct, said DNA construct being present in a host cell, in order for the element to be in a context appropriate for hormone responsiveness.

Claims 19-21 and 49 are indefinite because the preamble recites that the DNA construct comprises “a structural gene and a promoter upstream of the structural gene”, but the DNA construct used to transfect the host cell does not comprise a structural gene. Thus, the preamble is in conflict with the rest of the claim and the metes and bounds of the claim are not clearly set forth. It is suggested that the claim language recite in part (a) “providing a DNA construct comprising at least one enhancer element consisting of the nucleotide sequence TTCTGAGAA upstream from a promoter and a structural gene downstream from said promoter”.

Claims 19-21 and 49 are indefinite in their recitation of “transfecting a eukaryotic host cell wherein transcription can occur to incorporate the DNA construct” because transcription is a process by which DNA is transcribed into RNA. It is not a process for incorporating a DNA construct.

Claims 19-21 and 49 are indefinite in their recitation of the phrase “to incorporate the DNA construct” in part (b) because it is unclear where the DNA construct is incorporated. It is suggested that the claim language recite “transfecting a eukaryotic host cell to incorporate the DNA construct into the genome of the host cell”.

Claims 44 and 45 are indefinite because the arrangement of the genetic elements (i.e., the enhancer, promoter, and structural gene) are not specified. As discussed above, the arrangement of the genetic elements is critical to the operability of the invention. Claim 44 has been amended to recite “[a]n isolated DNA construct comprising a structural gene, a promoter and six repeats of an enhancer, wherein the enhancer consists essentially of the sequence TTCTGAGAA.”

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, and 49 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yoon et al. (1990) for reasons of record advanced in the previous Office Action mailed 4/26/00 (Paper No. 16) and in the Office Action mailed 11/22/00 (Paper No. 19).

Applicants argue that Yoon et al. do not teach a method wherein a DNA construct is provided with at least one enhancer element consisting of the nucleotide sequence TTCTGAGAA upstream of the promoter and is then incorporated into the eukaryotic host cell by transfection. However, as argued previously, the claims continue to read on the method disclosed by Yoon et al. because the constructs described by Yoon et al. include the nucleotide sequence TTCTGAGAA and the instant claim recites transfecting a cell with a DNA construct **with at least one enhancer element consisting of the nucleotide sequence TTCTGAGAA upstream of the promoter**. However, since the enhancer element is located upstream of the promoter, some spacing between the promoter and the enhancer element is to be expected. The constructs described by Yoon et al. are of this type (i.e., the enhancer element is not directly adjacent to the promoter, rather there are a number of nucleotides that act as spacers between the enhancer and the promoter). Yoon et al. need not teach a segment smaller than the 50 bp segment set forth as SPI-GHRE which is responsive to growth hormone, because the segment that they used included the nucleotide sequence recited in the claim and the arrangement of genetic elements (i.e., enhancer, promoter, structural gene) is the same as that described in the instant specification. The enhancer element that Yoon et al. used did in fact "consist of" TTCTGAGAA despite the

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fact that they included some flanking sequences in their constructs as well. It is not necessary that Yoon et al. recognize or teach the minimal sequence that will function as an enhancer, because no matter how long the piece of DNA is initially, once it is incorporated into the DNA construct it necessarily becomes flanked by other nucleotides.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lindquester et al. (1989) for reasons of record advanced in the Office Action mailed 4/26/00 (Paper No. 16) and in the Office Action mailed 11/22/00 (Paper No. 19).

The claims are directed to an expression vector comprising at least one enhancer element consisting essentially of the nucleotide sequence TTCTGAGAA, an isolated eukaryotic host cell containing the expression vector, and a DNA construct comprising a promoter, a structural gene and at least one enhancer element comprising the sequence TTCTGAGAA.

Applicants argue that Lindquester et al. does not specifically disclose that the sequence TTCTGAGAA acts as an enhancer. However, Lindquester et al. need not disclose the function of the sequence because the claims are directed to compositions that include this sequence. The function of the element is an inherent property of the composition. See MPEP 2112.01. When the structure recited in a

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reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. Thus, the function of the enhancer element is considered an inherent property of the element.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*

ANNE-MARIE BAKER  
PATENT EXAMINER